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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/665,303	09/19/2000	John T. Santini Jr.	17648-0014	5521
29052	7590	02/25/2004	EXAMINER	
SUTHERLAND ASBILL & BRENNAN LLP 999 PEACHTREE STREET, N.E. ATLANTA, GA 30309			THISSELL, JEREMY	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 02/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/665,303

Applicant(s)

SANTINI JR. ET AL.

Examiner

Jeremy T. Thissell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 and 42-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3-7, 11, 14, 49, 52 and 56 is/are allowed.
- 6) ☒ Claim(s) 1, 2, 8, 10, 12, 15, 16, 18, 19, 21, 23, 24, 43-47, 50, 51 and 53-55 is/are rejected.
- 7) ☒ Claim(s) 13, 26 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

Claims 1, 2, 8, 10, 12, 15, 16, 18, 19, 21, 23, 24, 43-47, 50, 51, and 53-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roth et al (WO 97/34697).

Note that this publication is written in German. Corresponding US Patent No. 6,114,658, may be used for reference as it seems to be a direct translation. The examiner has included several Babelfish translations (internet translator) of select paragraphs from the WO document, to demonstrate the correlation between the two documents. These are unofficial and imperfect, but are provided for a general idea, particularly with regard to several pertinent paragraphs. If the ensuing prosecution merits, an official translation may be obtained. However, for now, the examiner will refer to text in the US patent for purposes of convenience to both parties.

Roth teaches a multi-layer substrate having a reservoir with an encapsulated material, wherein the reservoir has a cap that is destroyed by an electrical heating element. (US '658: col. 2, lines 29-30) Roth does not explicitly state that the device contains a drug, but does teach that it is known in the art to encapsulate pharmaceuticals in this manner. (col. 1, line 10) Further it is well-known to implant such a drug-carrying microsystem into a patient. Further still, it is obvious to a skilled artisan to use any number of different drugs and controlled release patterns. Roth teaches a indicator material (aka diagnostic reagent) in the reservoir for sensing purposes.

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WO 97/34697, Pg 1, Para 2, 1st Sent (compare translation to US '658 Col. 1, L. 9-10)

Auf vielen gebieten werden empfindliche materialien, z.B. chemische indikormaterialien, katalysatoren, medikamente, eingesetzt.

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Babel Fish Translation

in English:

On many sensitive materials, e.g. chemical indicator materials, will order catalysts, medicines, begun.

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Auf vielen gebieten werden empfindliche materialien, z.B. chemische indikormaterialien, katalysatoren, medikamente, eingesetzt.

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Page 3, last para (compare translation to '658 col. 2, lines 21-30, esp. lines 29-30).

Die vorliegende erfindung schafft eine vorrichtung zur gekapselten aufnahme eines materials, die einen eine ausnehmung zur aufnahme des materials aufweisenden in mikrosystemtechnik gebildeten grundkörper, eine den grundkörper überspannende, in mikrosystemtechnik oder dünnfilmtechnologie implementierte membran zur kapselung des materials in der ausnehmung des grundkörpers, und eine elektrisch betätigbare heizeinrichtung zum zerstören der membran, um das material freizulegen aufweist.

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Babel Fish Translation

In English:

The available invention creates a device for the totally enclosed admission of a material, which exhibits a recess for the admission of the material exhibiting in micro system engineering formed more grundkörper, the more grundkörper überspannende in micro system engineering or dünnfilntechnologie implemented diaphragm for the packaging of the material in the recess grundkörper, and an electrically betätigbare heating mechanism to the zerstören diaphragm, around the material freizulegen.

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Die vorliegende erfindung schafft eine vorrichtung zur gekapselten aufnahme eines materials, die einen eine ausnehmung zur aufnahme des materials aufweisenden in mikrosystemtechnik gebildeten grundkörper, eine den grundkörper überspannende, in

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Page 5, last line—page 6, 1st paragraph (compare transl to '658 Col. 3, lines 29-45)

Ein gassensorbauelement, das in den figuren 1 und 2 in seiner gesamtheit mit dem bezugszeichen 10 bezeichnet ist, umfaßt einen trager 1, welcher beispielsweise aus quarz besteht, an den die mebelement (z.b. leiterbandstrukturen, mosfet, saw u.a.) 2, 3 einer interdigitalstruktur zur kapazitäts- und/oder widerstandsmessung mit zugehörigen verbindungsleitungen 2b, 3b und Anschlußflächen 2a, 3a aufgebracht sind. Die Interdigitalstruktur ist mit einem indikormaterial 6 bedeckt. Bei dem hier gezeigten Ausführungsbeispiel des gassensorbauelementes 10 handelt es sich bei dem indikormaterial um 3-amino-propyltrimethyloxysilan, welches an luft nur eine begrenzte lebensdauer von drei monaten hat. Es ist deshalb erwünscht, die indikormaterialschicht erst kurz vor ihrem einsatz in kontakt mit der umgebungsluft zu bringen, um die volle lebensdauer der indikormaterialschicht zur verfügung zu haben.

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in English:

A gas sensor element, das in the figures 1 and 2 in its whole with the reference symbol 10 is designated, umfasst einen trager 1, which consists for example of quartz, outer a that mebelement (e.g. leiterbandstrukturen, mosfet, saw among other things) 2, 3 of an interdigital structure for the kapazitäts and/or resistance test with zugehörigen leiter lines 2b, 3b and Anschlußflächen 2a, 3a are applied. The interdigital structure is covered with an indicator material 6. With the export example of the element of building of gas sensors 10 shown here it concerns with the indicator material 3-amino-propyltrimethyloxysilan, which has a limited life span of three months at air only. It is therefore erwünscht to bring the indicator material layer only briefly before its employment in contact with the ambient air in order to have the full life span of the indicator material layer to the joining.

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Ein gassensorbauelement, das in den figuren 1 und 2 in seiner gesamtheit mit dem bezugszeichen 10 bezeichnet ist, umfaßt einen trager 1, welcher beispielsweise aus quarz besteht, an den die mebelement (z.b. leiterbandstrukturen, mosfet, saw u.a.) 2, 3

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Page 6, first full para (compare '658 col. 3, lines 46-61)

Zum Zwecke der Kapselung ist der Träger 1 an seiner mit dem Indikatormaterial 6 versehenen Seite mit einer Membranhaltestructur 4 versehen, die bei dem hier gezeigten Ausführungsbeispiel aus einem Siliziumwafer besteht, in dem die Ausnehmung 8 durch übliche photolithographische und Halbleitertechnische Methoden eingearbeitet ist. Für einen Fachmann auf dem Gebiet der Mikrosystemtechnik bedarf es keiner Erläuterung, daß Methoden zur Herstellung von einer Membranhaltestructur überspannenden Membran in der Mikrosystemtechnik üblich sind und daß hierbei üblicherweise eine Membran 5 zunächst auf eine Haltestruktur 4 durch photolithographische und Halbleitertechnische Maßnahmen eingebracht wird.

Allowable Subject Matter

Claims 13 and 26 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 3-7, 11, 14, 49, 52, and 56 are allowed.

Response to Arguments

Applicant's arguments filed 20 November 2003 have been fully considered but they are not persuasive. Applicant argued that Roth does not teach an implantable encapsulated drug device, contending that Roth teaches in vitro testing of an encapsulated drug. However, Roth teaches a micro or miniaturized device. Pharmaceuticals are, by their very nature, intended to be administered to the body, and thus are only encapsulated in miniaturized devices for one reason, being placed in the body. So whether Roth is merely testing the device or not, one of ordinary skill would have found it obvious to implant the encapsulated drug device.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

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mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contacts

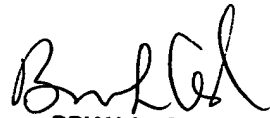
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeremy T. Thissell whose telephone number is (703) 305-5261. The examiner can normally be reached on 8:30-7:00 Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached at (703) 308-3552. The fax phone numbers for all fax communications is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

jt

February 23, 2004


BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700